REMARKS

Claims 1, 2, 4-6, 9-16, 18, 19, 25 and 26 are pending in the subject application. Applicants have hereinabove added new claims 27-30 and amended claim 19. Support for these amendments may be found inter alia in the specification as follows: claims 27-31: originally filed claims 21-24, respectively. The amendments to claim 19 merely introduce minor grammatical and format changes. These amendments do not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 1, 2, 4-6, 9-16, 18, 19, 25 and 26-30 will be pending.

In the Office Action, the Examiner restricted pending claims 1, 2, 4-6, 9-16, 18, 19, 25 and 26 to one of the following allegedly distinct inventions under 35 U.S.C. §121:

I. Claims 1, 2, 4 and 11, drawn to a method for determining the aggressiveness of a prostate carcinoma, diagnosing benign prostate hyperplasia, predicting the life span of a patient with prostate carcinoma by detecting the presence of p27 RNA or protein; and a nucleic acid molecule encoding a p27 protein;

II. Claims 5-8, drawn to methods involving gene therapy to increase or prolong the life span of a patient with prostate carcinoma by inducing expression of p27 protein or introducing nucleic acid encoding p27 protein;

III. Claim 9, drawn to a method for prolonging the life span of a patient with prostate carcinoma by introducing a

substance that stabilizes a p27 protein;

IV. Claim 10, drawn to a method for prolonging the life span of a patient with prostate carcinoma by introducing a substance that stabilizes a p27 protein;

V. Claim 12, drawn to p27 protein;

VI. Claim 13, drawn to a substance that stabilizes p27 protein;

VII. Claim 14, drawn to a method for determining the rate of proliferation of prostate cancer by detecting the presence of p21 protein;

VIII. Claim 15, drawn to a method for determining the rate of proliferation of prostate cancer by detecting the presence of mdm2 overexpression;

IX. Claim 16, drawn to a method for determining whether a prostate cancer is metastatic by detecting the overexpression of cyclin D1;

X. Claim 18, drawn to a method for detecting tumor recurrence by detecting the overexpression of p16;

XI. Claim 19, drawn to a method for treating prostate cancer by administering anti-Her/neu antibody; and

XII. Claims 25-26, drawn to methods of diagnosing prostate cancer by measuring Her-2/neu expression.

In response, applicants hereby elect Group XI, claim 19, drawn to a method for treating prostate cancer by administering anti-Her/neu antibody, with traverse for prosecution at this time. New claims 27-30 are directed to embodiments of the subject matter of claim 19, and thus, applicants understand this election of Group XI to encompass claims 19 and 27-30.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination can be made without serious burden.

The inventions of Groups I-XII are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subject matter claimed. The inventions of Groups I-XII are drawn to compositions and methods related to the diagnosis and treatment of prostate cancer using various cancer-associated proteins. Applicants therefore maintain that groups I-XII are not independent and restriction is not proper.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups I-X and XII would not require a serious burden once the prior art relevant to Group XI has been identified.

Therefore, there would be no serious burden on the Examiner to examine Groups I-XII together in the subject application. Hence, the Examiner must examine these Groups on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121 and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the $1,014.00 sum, which includes the additional claim fee and the five-month extension of time fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

4/21/04

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